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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ZARA, JANE J	
ART UNIT	**PAPER NUMBER**
1635	20

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/432,820	Applicant(s) Kapoor et al
	Examiner Jane Zara	Art Unit 1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Nov 6, 2002* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *24-33 and 41-52* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) *41-50 and 52* is/are allowed.

6) ☒ Claim(s) *24-33 and 51* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This Office action is in response to the communications filed May 6, 2002 and November 6, 2002, Paper Nos. 15 and 19.

Claims 24-33, 41-52 are pending in the instant application.

Continued Prosecution Application

The request filed on November 6, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/432,820 is acceptable and a CPA has been established. An action on the CPA follows.

Response to Amendments

Withdrawn Rejections

Rejection of claims 41-49 under 35 U.S.C. 112, first paragraph, for lacking adequate written description and for lacking scope of enablement, are hereby withdrawn in light of Applicant's amendments filed May 6, 2002, Paper No. 15.

Maintained Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention

Claims 24-33 and 51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record set forth in the Office action mailed January 1, 2001, Paper No. 9.

The specification does not describe elements which are essential to various functions of the claimed invention, which elements include those which are essential to the definition of antigenic determinant of a homologue of SEQ ID No: 2. The specification and claims do not indicate what distinguishing attributes are concisely shared by the members of the genus comprising antigenic determinants, including those antigenic determinants of homologues of SEQ ID NO: 2. The disclosure does not clarify what the common attributes are encompassed by antigenic determinants of SEQ ID NO: 2, nor the antigenic determinants of homologues of SEQ ID NO: 2. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant, because a significant number of structural differences between members of the given genus is permitted. Concise structural features that could distinguish structures or sequences within the genus from others are missing from the disclosure. No common structural attributes identify the members of the genus comprising antigenic determinants of SEQ ID NO: 2, or antigenic determinants of homologues of SEQ ID NO: 2, whereby an antigenic distinction exists between antigenic regions of SEQ ID NO: 2 and its homologous. No common structural

attributes identify the members of the genus comprising homologues of SEQ ID NO: 2, which homologues are antigenically distinct from other homologous of ion motive ATPases, including other bacterial homologues. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general guidance is what is needed. The specification fails to teach or adequately describe a representative number of species in the claimed genus such that the common attributes or characteristics concisely identifying members of the proposed genus are exemplified, and because the genus is highly variant, the description provided is insufficient. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus claimed. Thus, Applicants were not in possession of the claimed genus.

Claims 24-33 and 51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting the presence of antibodies to *Mycobacterium* comprising the detection of polypeptide encoded by SEQ ID NO: 2, and being enabling for detecting the presence of the polypeptide of SEQ ID NO: 2 in a sample using antibodies, does not reasonably provide enablement for a method of detecting the presence of antibodies or protein lysate of *Mycobacteria* comprising the detection of antigenic determinants of any and/or all homologues of SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to methods of detecting the presence of antibodies to *Mycobacteria* in a biological sample comprising combining said sample with the protein comprising SEQ ID NO: 2 or any and/or all homologues of SEQ ID NO: 2, as well as methods of detecting the presence of the protein of SEQ ID NO: 2 in a sample comprising detection of antibodies which bind to SEQ ID NO: 2, or any and/or all homologues of SEQ ID NO: 2, whereby antibody binding is detected and *Mycobacterial* presence is detected.

The following factors have been considered in determining that the specification does not enable the skilled artisan to make and/or use the invention over the scope claimed.

The state of the prior art and the predictability or unpredictability of the art. The instant specification discloses difficulties which exist in attempts to generate methods of immunodiagnosing *Mycobacteria*, which difficulties include a lack of sensitivity and specificity in detecting *Mycobacterial* antigens, and whereby such shortcomings are due to inaccessibility of antigens and host immune suppression due to immunomodulatory cell wall constituents of *Mycobacteria*. Furthermore, methods of detecting clear antigenic distinctions between various *Mycobacterial* strains are lacking in the art for the reasons cited above and because antigenic homologues have been identified among some strains of *Mycobacteria*. (See pages 2-6 of the instant specification.)

The amount of direction or guidance presented in the specification AND the presence or absence of working examples. Applicants have not provided guidance in the specification toward a method of detecting the presence of antibodies to any and/or all

Mycobacteria, comprising the detection of antibodies in a sample, which antibodies bind to SEQ ID NO: 2 and/or all homologues of SEQ ID NO: 2, nor of detecting the presence of Mycobacterium in a biological sample comprising detecting any and/or all homologues of SEQ ID NO: 2 in the sample.

The specification teaches the detection of antibody binding to the purported translation product comprising SEQ ID NO: 2, which antibodies have been obtained from patients which have been exposed to *Mycobacterium tuberculosis*. The specification fails to teach the successful detection of *Mycobacterial* strains upon antibody binding to SEQ ID NO: 2 and/or all homologues of SEQ ID NO: 2. One skilled in the art would not accept on its face the examples given in the specification of antibody detection upon binding to a translation product obtained from the expression of *M. bovis* genomic library fragments, whereby the presumed translation product comprises SEQ ID NO: 2, and which antibodies are obtained from patients exposed to *M. tuberculosis*, as being correlative or representative of the ability to detect antibodies directed to *Mycobacterial* strains comprising the detection of antibodies which bind to antigenic determinants of any and/or all homologues of SEQ ID NO: 2, in view of the lack of guidance in the specification and known unpredictability associated with the antigenic distinctions or antigenic similarities which exist between various *Mycobacterial* strains whereby antibodies which are generated in an individual upon exposure to *M. tuberculosis*, and also bind to the purported translation product SEQ ID NO: 2 and/or all of its homologues, also bind in a quantitatively or qualitatively detectable manner to antibodies directed to all *Mycobacterial* strains. The

specification as filed fails to provide any particular guidance which resolves the known unpredictability in the art associated with the ability to detect antibodies directed to any and/or all *Mycobacteria*, whereby such antibodies also bind SEQ ID NO: 2 and/or all of its homologues. The specification as filed fails to provide any particular guidance which resolves the known unpredictability in the art associated with the ability to determine the antigenic determinants of any and/or all homologues of SEQ ID NO: 2, whereby antibody binding is indicative of *Mycobacteria*.

The breadth of the claims and the quantity of experimentation required. The breadth of the claims is very broad. The claims are drawn to methods of detecting antibodies which bind to any and/or all *Mycobacteria* comprising combining a biological sample with the purported translation product SEQ ID NO: 2 and/or all of its homologues, or comprising combining recombinant protein encoded by SEQ ID NO: 2, and any and/or all homologues of SEQ ID NO:2, whereby antibody binding is detected and the presence of *Mycobacteria* is also detected. In order to practice the invention over the scope claimed, it would require undue trial and error and undue experimentation beyond which is taught in the specification to practice the invention drawn to the detection of antibodies binding to SEQ ID NO: 2, as well as any and/or all homologues of SEQ ID NO: 2, whereby such antibody binding is indicative of the presence of *Mycobacteria*. The quantity of experimentation required to practice the invention as claimed would require the *de novo* determination of the antigenic determinants of any and/or all homologues of SEQ ID NO: 2, whereby antibody recognition reflects *Myobacterial* presence.

The specification teaches the ability to detect antibodies which were obtained from patients exposed to *Mycobacterium tuberculosis*, which antibodies also bound to the translation product of the genomic fragment obtained from *M. bovis* as described in the instant specification, which translation product is embodied in SEQ ID No: 2. The specification also teaches the ability to detect antibody binding to protein lysate in a sample, which lysate comprises protein encoded by SEQ ID NO:2. Since the specification fails to provide any particular guidance for the successful detection of antibodies which bind to any and/or all antigenic determinants of any and/or all homologues of SEQ ID NO: 2, and since determination of the antigenic determinants of all homologues of SEQ ID NO: 2 is highly unpredictable, it would require undue experimentation to practice the invention over the scope claimed.

Allowable Subject Matter

Claims 41- 50 and 52 are allowed.

Conclusion

This is a CPA of applicant's earlier Application No. 09/432,820. All rejected claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in

this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

RAM R. SHUKLA, PH.D
PATENT EXAMINER

JZ

January 27, 2003